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Customer No. 22,852  
Attorney Docket No. 05394.0022

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Stewart COLE et al. )  
Application No.: 10/510,021 )  
Filed: October 1, 2004 ) Group Art Unit: 1645  
For: IDENTIFICATION OF VIRULENCE )  
ASSOCIATED REGIONS RD1 AND RD5 )  
LEADING TO IMPROVE VACCINE OF M. )  
BOVIS BCG AND M. MICROTI )  
Examiner: Not Yet Assigned

**Commissioner for Patents**  
**P.O. Box 1450**  
**Alexandria, VA 22313-1450**

Sir:

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)**

Pursuant to 37 C.F.R. §§1.56 and 1.97(b), applicants bring to the Examiner's attention the documents listed on attached Form PTO/SB/08 and cited in the international search report. Copies of the listed documents are attached. Applicants respectfully request that the Examiner consider the documents listed on attached Form PTO/SB/08 and indicate that they were considered by making an appropriate notation on this form.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits for the above-referenced application.

Enclosed is an English-language international search report from the European Patent Office in the PCT international application, from which this national phase U.S. application is derived.


This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and applicants determine that the cited documents do not constitute "prior art" under United States law, applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents. Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

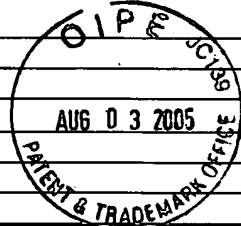
FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: August 3, 2005

By:   
Ernest F. Chapman  
Reg. No. 25,961

Enclosures  
EFC/FPD/blc

IDS Form PTO/SB/08: Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
Sheet		1	of	1	Application Number 10/510,021
					Filing Date October 1, 2004
					First Named Inventor Stewart COLE
					Art Unit 1645
					Examiner Name Not Yet Assigned
					Attorney Docket Number 05394.0022



U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS					
Examiner Initials	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

**Note: Copies of the U.S. Patent Documents are not Required in IDS filed after October 21, 2004**

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation <sup>6</sup>
		WO 99/04005	01-28-1999	GICQUEL et al.		
		WO 99/45119	09-10-1999	JENSEN et al.		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation <sup>6</sup>
		MAHAIRAS et al., "MOLECULAR ANALYSIS OF GENETIC DIFFERENCES BETWEEN MYCOBACTERIUM BOVIS BCG AND VIRULENT M. BOVIS", Journal of Bacteriology, Vol. 178, No. 5, pp. 1274-1282, (March 1996).	
		ANDERSEN et al., "RECALL OF LONG-LIVED IMMUNITY TO MYCOBACTERIUM TUBERCULOSIS INFECTION IN MICE", J. Immunol., Vol. 154, No. 7, pp. 3359-3372, (1995), taken from DATABASE NCBI, XP-002209499, (April 27, 1996).	
		ANDERSEN et al., "REGULATORY POLYNUCLEOTIDE CONTAINING M. TUBERCULOSIS 1hp/orfic OPERONS", DATABASE EBI, XP-002209498, (5 pages), (June 7, 1999).	
		BERTHET et al., "A MYCOBACTERIUM TUBERCULOSIS OPERON ENCODING ESAT-6 AND A NOVEL LOW-MOLECULAR-MASS CULTURE FILTRATE PROTEIN (CFP-10)", Microbiology, Vol. 144, pp. 3195-3203, (1998).	
		BERTHET et al., "MYCOBACTERIUM TUBERCULOSIS H37Rv esat6 PROMOTER REGION, L45 ANTIGEN HOMOLOGOUS PROTEIN LHP (1hp) GENE, COMPLETE cds, AND EARLY SECRETED ANTIGENIC TARGET 6 kDa (esat6) GENE, PARTIAL cds.", DATABASE EBI, XP-002209500, (2 pages), (June 29, 1998).	
		ZHANG YE et al., "THE SIGNALLING PATHWAY FOR BCG-INDUCED INTERLEUKIN-6 PRODUCTION IN HUMAN BLADDER CANCER CELLS", Biochemical Pharmacology, Vol. 63, No. 2, pp. 273-282, (2002).	
		MUSTAFA, "BIOTECHNOLOGY IN THE DEVELOPMENT OF NEW VACCINES AND DIAGNOSTIC REAGENTS AGAINST TUBERCULOSIS", Current Pharmaceutical Biotechnology, Vol. 2, No. 2, pp. 157-173, (2001).	
		BROSCH et al., "A NEW EVOLUTIONARY SCENARIO FOR THE MYCOBACTERIUM TUBERCULOSIS COMPLEX", PNAS, Vol. 99, No. 6, pp. 3684-3689, (2002).	
		BROSCH et al., "THE EVOLUTION OF MYCOBACTERIAL PATHOGENICITY: CLUES FROM COMPARATIVE GENOMICS", TRENDS in Microbiology, Vol. 9, No. 9, pp. 452-458, (2001).	

Examiner Signature	Date Considered
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**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.